

APPLICATION FOR LETTERS PATENT

Title: MIMICKING THE METABOLIC EFFECTS OF CALORIC RESTRICTION
BY ADMINISTRATION OF GLUCOSE ANTIMETABOLITES

This is a continuation-in-part of the application Ser. No. 08/889,877 filed July 8, 1997, now ~~pending~~-abandoned.

Field of the Invention:

This invention relates to the use of glucose anti-metabolites to alter utilization of glucose or other energy sources and to mimic metabolic effects of caloric restriction.

Background of the Invention:

Biological theories correctly predict the finding that a restriction of caloric intake by food deprivation slows down certain undesirable cellular processes in laboratory animals, many associated with aging and age-related diseases.

It is also known that hyperinsulinemia is a risk factor associated with several such disease processes, including heart disease and diabetes (Balkau and Eschwege. Diabetes Obes. Metab. 1 (Suppl 1): S23-31, 1999). The avoidance of hyperinsulinemia should be a goal for treatment of many individuals.

Glucose anti-metabolites such as 2 deoxy-D-glucose are compounds related to glucose. However, due to structural differences from glucose such compounds block or inhibit certain aspects of carbohydrate metabolism (Rezek, et al., J. Nutr. 106:143-157, 1972). These anti-metabolites exert a number of physiological effects, including reduction of body weight,

Response to Objections and Rejections

The specification has been amended to reflect the change in status of the priority document.

The Examiner has indicated that he believes the title is not descriptive. No particulars relating to this statement are noted. It is believed the title does reflect the invention as the inventors intended. Should this objection be maintained, it is respectfully requested that the examiner provide further enlightenment as to why the description is deemed inappropriate.

Claims 1-8 have been rejected under 35 U.S.C. 102(b) as being anticipated by applicants' admissions. The rejection is respectfully traversed. We do not argue with the allegation that the immediate blocking of glucose utilization is taught. However, the use of the agents as claimed for obtaining benefits of caloric restriction are not suggested. Hence, the invention as claimed is neither taught nor claimed therein.

Claims 1, 2 and 8 were rejected under 35 U.S.C. 102(b) as anticipated by Nutrition Reviews. The rejection is respectfully traversed. The teaching of that reference is that, in cases of recurrent hypoglycemic conditions, mannoheptulose may be used in a therapeutic manner to treat inoperable insulinoma, leucine-sensitive hypoglycemia or severe reactive hypoglycemia. First, the claim under consideration is to use to obtain beneficial biological results seen in caloric restriction. It is not seen how a method of treating hypoglycemia suggests use to obtain benefits obtained by restriction of caloric intake.

Claims 1 and 3 have been rejected under 35 U.S.C. 102(b) as anticipated by Francesconi teaching reduced availability of tissue glucose. The rejection is respectfully traversed. The reference teachings relate to use of 5-thio-D-glucose to lower temperature. In fact, the teaching relates to use of dosage in

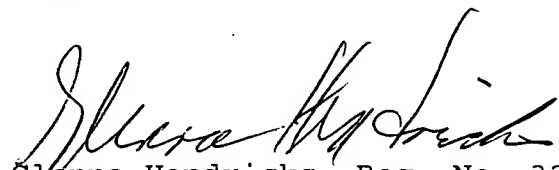
such high levels as to induce death, well beyond the expected effect from mere restriction of caloric intake. The study does not even suggest use in accord with the claimed invention.

Claims 1, 6 and 7 have been rejected under 35 U.S.C. 102(b) as being anticipated by Sakata. The rejection is respectfully traversed. The article by Sakata, et al, teaches use of compounds to for inhibiting action on glycogenesis and was found to increase eating and ambulation. That is not related to the claimed invention, which is to obtain benefits such as those which result from caloric restriction.

Finally, the claims have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The rejection is respectfully traversed. The examiner has stated the experimentation needed to practice the invention is undue. First, of all, the dosage range for the agents is disclosed on pages 9 and 10, along with guidelines on how to choose preferred dosage. The most preferred agent was tested on beagle dogs, which are standard means for testing such agents before they are administered to humans. Hence, it can not be said the claims have not been enabled.

It is believed the claims are now in condition for allowance. If discussion would facilitate prosecution of this application, the Examiner is invited to contact the Applicant's representative at (703) 425-8405.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Glenna Hendricks", written in dark ink.

Glenna Hendricks, Reg. No. 32,535